European Medicines Agency
Press office

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PRESS RELEASE
Defect in Herceptin vials identified but supply for patients is maintained

The European Medicines Agency has been made aware of a defect with vials of Herceptin (trastuzumab). The Agency's Committee for Medicinal Products for Human Use (CHMP) has agreed a plan for the visual re-inspection of vials and for the replacement of defect vials with the marketing authorisation holder, Roche. The aim of this plan is to identify and remove defective vials, while maintaining supply of the medicine, so that patients do not have to interrupt their treatment.

Herceptin is packaged in a 15 ml clear glass vial. The defect stems from a fault during the packaging process, which has resulted in cracks in the shoulders of the vials in some cases. There is a risk that cracked vials may lead to a loss in sterility, which can cause infections in patients. While testing indicates that the cracks have no effect on the sterility of the product, the company has been advised as a precautionary measure to re-inspect the vials and replace the cracked vials. Only vials packaged since March 2006 are affected by the defect.

Roche has received about 20 complaints of cracked vials from hospitals in France, Germany, Ireland and the United Kingdom. In most cases, the vials had broken when the flip-top cap was removed. In two cases only cracks were reported. Following the reports, the company inspected 13,000 packaged vials, and found that 1 in 1,000 had a cracked bottleneck. Cracked vials may still be in circulation.

The marketing authorisation holder has provided instructions on how to examine vials for potential cracks to every hospital and specialised treatment centre where Herceptin is used. Roche has further committed to ensure that each hospital reports back its findings and does not use any affected vials found. This only affects batches distributed before November 2006.

The Agency has asked the marketing authorisation holder to submit weekly status reports on the progress of the recall activities and the numbers of defective vials identified pending resolution of the situation. Specific good manufacturing practice (GMP) inspections will also be carried out.

Herceptin was approved in Europe in 2000. It is currently authorised for the treatment of patients with breast cancer whose tumours overexpress HER2.

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Notes
1. More information about Herceptin, including its full indication, is available in the European Public Assessment Report (EPAR), which can be found here.
2. The detailed instructions for inspection of the vials can be found here.
3. This press release together with other information about the European Medicines Agency can be found on the EMEA website: www.emea.europa.eu

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